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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/585,820	06/01/2000	Thomas J. Mercolono	CDS-221	4698

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EXAMINER
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GRUN, JAMES LESLIE

ART UNIT	PAPER NUMBER
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1641

16

DATE MAILED: 05/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/585,820**

Applicant(s)  
**MERCOLINO et al.**

Examiner  
**James L. Grun, Ph.D.**

Art Unit  
**1641**



-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 Dec 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 16, 20, 22, 23, and 25-51 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16, 20, 22, 23, and 25-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

The amendment filed 23 December 2002 is acknowledged and has been entered. Claims 1-15, 17-19, 21, and 24 have been cancelled. Claims 16, 20, 22, 23, and 25-51 remain in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16, 20, 22, 23, 25-41, 44, 47, and 49-51 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16, 20, 29, 22, 23, and 49 positively claim identical subject matter as claimed in claims 25, 26, 30, 27, 28, and 50, respectively, and differ only in the intended use recitations of their preambles, recitations which do not serve to distinguish the same subject matter from itself.

In claims 29, 30, 33, 39, and claims 22, 23, 27, 28, 34, 35, 40, and 41 dependent thereupon, "the single test" lacks antecedent basis.

In claims 29, 30, 33, 39, 44, and 47, the interrelationships of the components are not clear because it is not clear how the recited alternatives relate to the previously recited "single column."

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In claims 31-35 and 51, it is not clear what is being determined because the interrelationships of antigens borne on the cell populations to reverse ABO type determined in step d) are not clear.

In claims 36-41 the interrelationships of the steps and components are not clear, for example because: the relationship of antibody to sample or admixture is not clear; and, the relationship of antibody to first or second antigen or to agglutinate is not clear.

Applicant's arguments filed 23 December 2002 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated prior rejections for the reasons repeated above.

Applicant urges that claims 16 and 25 do not claim identical subject matter because the preamble of claim 25 indicates narrower subject matter than that of claim 16. This is not found persuasive because the preambles of these claims have not been accorded any patentable weight which distinguishes the claimed subject matter because the preambles merely recite the purpose of identically claimed processes for reverse ABO typing, not for alternative processes for determination of different scopes of antibodies to erythrocyte antigens as would appear applicant's allegation.

With regard to claims 36-41, applicant asserts that pages 24-25 of the specification set forth the method of screening for determination of antibodies. This is not found persuasive because claims must particularly point out and distinctly claim the subject matter which applicant

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regards as the invention and, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

Claims 42-44 and 46-47 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Ullman (U.S. Pat. No. 4,584,277) for reasons of record.

Applicant's arguments filed 23 December 2002 have been fully considered but they are not deemed to be persuasive. Applicant urges that newly presented recitations of intended use for a column or for the reagents in particular method steps serve to distinguish the subject matter of the instant claims from the reagents disclosed in the reference. This is not found persuasive because recitations of intended use are accorded patentable weight only to the extent that they limit the actual components of the kit; in the instantly rejected claims the intended use does not affect the components in any way which distinguishes over the subject matter taught or suggested by the reference.

Claims 36-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Yves [Lapierre] et al (U.S. Pat. No. 5,338,689) for reasons of record.

Claims 36-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Chachowski et al (U.S. Pat. No. 5,552,064) for reasons of record.

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Claims 36-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chachowski et al (U.S. Pat. No. 5,552,064) in view of Shen et al (U.S. Pat. No. 5,594,808) for reasons of record.

Applicant's arguments filed 23 December 2002 have been fully considered but they are not deemed to be persuasive. Applicant urges that the claims as amended overcome the teachings of the references of Yves [Lapierre] et al (U.S. Pat. No. 5,338,689), alone, or Chachowski et al (U.S. Pat. No. 5,552,064), alone or as modified, because these references fail to show performance in a single column. This is not found persuasive for the instantly rejected claims because the recitation "in a single column" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

No claim is allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (703) 308-3980. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (703) 305-3399.

The phone numbers for official facsimile transmitted communications to TC 1600, Group 1640, are (703) 872-9306, or (703) 305-3014, or (703) 308-4242. Official After Final communications, only, can be facsimile transmitted to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. The above inquiries, or requests to supply missing elements from Office communications, can also be directed to the TC 1600 Customer Service Office at phone numbers (703) 308-0197 or (703) 308-0198.

  
James L. Grun, Ph.D.  
April 30, 2003

  
CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1600/64/  
5/2/03